4.0 510(K) SUMMARY

APR 5 2013

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.98.

Submitter Information

Name:	Covidien
Address:	15 Crosby Drive Bedford, MA 01730
Establishment Registration:	9615742
Name of contact person:	Jose Marquez Regulatory Affairs Manager Covidien 15 Crosby drive Bedford, MA 01730 USA Phone: (781) 839 1755
Date prepared:	March 20, 2013
Trade or proprietary name:	AccuMesh™ Positioning System
Common or usual name: **Classification name:** **Classification panel:**	Mesh Deployer Mesh, Surgical, Deployer General and Plastic Surgery (79)
Regulation:	21 CFR 878.3300
Product Code:	ORQ
Legally marketed devices to which equivalence is claimed:	o Accumesh Positioning System (510k cleared as the PatchAssist device – K101218 o Accumesh Positioning System PatchAssist Large (510k cleared as the PatchAssist device – K103269 o AccuMesh Positioning System – K123066

Reason for 510(k) submission:

To obtain market clearance on the Accumesh Positioning System with a component color addition of an orange ink.

Device description:

The AccuMesh Positioning System is a manual laparoscopic surgical instrument intended to facilitate hernia mesh delivery and placement in laparoscopic ventral hernia repair. It is comprised of two main sections: operation handle and deployment section which are connected via a tube. Included in the packaging configuration is a furling sleeve intended to assist the surgeons to furl the mesh tightly and rapidly over the AccuMesh positioning system.

Intended use of the device:

Intended to facilitate the delivery of soft tissue prosthetics during laparoscopic repair of soft tissue defects (e.g. hernia repair).

Indications for use:

Indicated to facilitate the delivery of soft tissue prosthetics during laparoscopic repair of soft tissue defects (e.g. hernia repair).

Summary comparing the technological characteristics of the subject and predicate devices:

The proposed colorant addition is on the central distal shaft found on the deployment frame. The central distal shaft on the deployment frame or the frame, itself, has not changed and is previously cleared in the AccuMesh (PatchAssist) device (K101218, K103269, and K123066) 510(k)s. Accumesh is intended to be used to facilitate the delivery of soft tissue prosthetics during laparoscopic repair of soft tissue defects (e.g. hernia repair). There are no changes to the technological characteristics as a result of the proposed colorant addition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter dated: April 5, 2013

Covidien
% Mr. Jose Marquez
Regulatory Affairs Manager
15 Crosby Drive
Bedford, Massachusetts 01730

Re: K130782
Trade/Device Name: AccuMesh™ Positioning System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: ORQ
Dated: March 20, 2013
Received: March 21, 2013

Dear Mr. Marquez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 INDICATION FOR USE STATEMENT

510(k) Number (if known): K130782

Device Name: AccuMesh™ Positioning System

Indications for Use: The AccuMesh Positioning System is intended to be used to facilitate the delivery of soft tissue prosthetics during the laparoscopic repair of soft tissue defects (e.g. hernia repair).

Prescription Use **X** AND/OR Over-the -Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130782